Remarks

Claims 1-5, 10-15 and 21-24 stand rejected under 35 U.S.C. § 103 over U.S. 2003/0180389 (Phillips) in view of *Journal of Pharmaceutical and Biomedical Analysis*, vol. 28, pp. 245-249 (Liang et al.).

Phillips discloses a granular composition that includes glucosamine, chondroitin sulfate and sulfur in an effervescent base. Phillips discloses that the glucosamine can be provided as glucosamine sulfate in a dose of 1500 mg. Phillips also discloses that the effervescent base includes an acidic ingredient and a basic ingredient.

Liang et al. disclose a photometric titration method to quantitate sodium chondroitin sulfate in raw materials and a COSEQUIN DS chewable tablet.

Claim 1 is directed to an effervescent composition that includes glucosamine, chondroitin derived from bovine, and an effervescent agent. In order to establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all of the claim limitations." M.P.E.P. 2142. In addition, there must be some suggestion or motivation to combine the references. *Id.* Chondroitin is available from a variety of sources. Chondroitin tends to have a bad taste, which renders it unpalatable (see, Applicants' Specification, page 1, lines 11-13). In effervescent compositions, taste is particularly important because the composition is added to water and ingested as a beverage. As a result, the taste buds are intimately exposed to the effervescent composition. Applicants have discovered effervescent compositions that include chondroitin derived from a bovine source are more palatable relative to effervescent compositions that include chondroitin obtained from shark and porcine sources[1] (*Id.*, page 4, lines 14-16). It is undisputed that Phillips does not teach chondroitin derived from a bovine source (see, March 26, 2007 Office action, page 2).

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[1] The March 26, 2007 Office action takes the position that there is no objective evidence in the record to support Applicant's allegations. March 26th Office action, page 2. Applicants respectfully disagree. The veracity of the statements in the above-captioned application are attested to by the Declaration submitted therewith. Moreover, it is well established that statements of an interested party cannot be dismissed on the mere basis that they are from an interested party. See, e.g., *Ex Parte Keyes*, 214 U.S.P.Q. 579 (Bd. App. 1982) ; *In re McKenna,* 97 U.S.P.Q. 348 (CCPA 1953). The record contains evidence, in the form of a sworn statement, that effervescent compositions that include chondroitin derived from a bovine source are more palatable relative to effervescent compositions that include chondroitin obtained from shark and porcine sources. This evidence must be considered in determining patentability.

Phillips also does not recognize the benefit of chondroitin derived from a bovine source. Accordingly, Phillips does not teach or suggest the effervescent composition of claim 1.

Liang et al. does not cure the deficiencies of Phillips. As a preliminary matter, the skilled artisan seeking to formulate an effervescent composition would have no reason to look to Liang et al. because Liang et al. has nothing to do with effervescent compositions and further fails to teach or suggest anything about formulating effervescent compositions. The proposed combination of Phillips and Liang et al. is further deficient in that Liang et al. is directed to a photometric titration method (see, Liang et al., abstract). Liang et al. disclose, "The purpose of this work was to develop a precise and accurate phototrode method that could be applied to the quantitation of chondroitin sulfate in a specific complex chewable tablet formulation (see, *Id.* at page 246). Liang et al. studied COSEQUIN DS tablets, which include glucosamine HCL, bovine sodium chondroitin sulfate, manganese ascorbate and flavoring agents (see, *Id.* at title and footnote 1). Nothing in Liang et al. teaches that chondroitin has a bad taste or that effervescent compositions that include chondroitin derived from a bovine source are more palatable relative to effervescent compositions that include chondroitin obtained from shark and porcine sources. Moreover, nothing in Liang et al. teaches or suggests including chondroitin derived from a bovine source in an effervescent composition. Furthermore, COSEQUIN DS tablets are chewable tablets designed for large dogs (see, COSEQUIN DS literature attached at Tab 1). Therefore the skilled artisan familiar with Phillips, which is directed toward effervescent compositions for human consumption, would have no reason to look to a journal article relating to the development of a method of determining the amount of sodium chondroitin sulfate in a raw material or in a chewable tablet designed for a dog. Thus, Liang et al. provides the skilled artisan with no reason to modify the effervescent composition of Phillips. Accordingly, a *prima facie* case of obviousness of claim 1 has not been made. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 103 over Phillips in view of Liang et al. is unwarranted and respectfully request that it be withdrawn.

Claims 2-5, 10-15 and 21-24 are distinguishable under 35 U.S.C. § 103 over Phillips in view of Liang et al. for at least the same reasons as set forth above in distinguishing claim 1.

Claims 6 and 7 stand rejected under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of U.S. 2001/0018082 (Fox).

The above discussion of Phillips and Liang et al. is incorporated herein.

Fox discloses effervescent compositions that provide calcium supplementation via a soluble calcium source. Fox also discloses that her effervescent compositions can include a primary calcium source and a secondary calcium source.

The rejection of claims 6 and 7 under 35 U.S.C. § 103 over Phillips in view of Liang et al., and in further view of Fox is based on the premise that the proposed combination of Phillips and Liang et al. teaches or suggests the effervescent composition of claim 1. Since this premise has been refuted above, the rejection of claims 6 and 7 cannot stand. For this reason alone, Applicants respectfully request that the rejection of claims 6 and 7 under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of Fox be withdrawn.

Claim 6 is further distinguishable under 35 U.S.C. § 103 over Phillips in view of Liang et al., and in further view of Fox for at least the following additional reasons. Claim 6 is directed to the effervescent composition of claim 1 and specifies that the composition further includes calcium lactate. It is undisputed that Phillips does not teach a composition that includes calcium lactate (see, October 6, 2006 Office action, page 7). In addition, contrary to the assertions in the October 6th Office action, Phillips does not suggest the incorporation of additional calcium as a nutritional supplement. Rather, Phillips teaches that it is preferable "to select a base which tastes good and, if possible has beneficial side effects." Phillips, para. [0033]. Phillips goes on to teach that a calcium carbonate base can provide additional calcium to strengthen bones. *Id.* However, nothing in Phillips teaches or suggests adding additional calcium beyond that which is provided as the primary effervescent base.

Liang et al. do not cure the deficiencies of Phillips. Nothing in Liang et al. teaches or suggests an effervescent composition that includes calcium lactate. Moreover, nothing in Liang et al. provides the skilled artisan with any reason to modify the effervescent compositions of Phillips to include calcium lactate.

Fox does not cure the deficiencies of Phillips and Liang et al. Fox discloses an effervescent composition that includes a primary calcium source and a secondary calcium

source (see, Fox, page 2, para. [0026]). Fox also discloses that the primary calcium source is calcium carbonate and that the secondary calcium source can include calcium lactate (*Id.*). The focus of Fox is on effervescent calcium supplements. The focus in Phillips, in contrast, is on the repair and maintenance of connective tissue in mammals. Fox does not teach or suggest including his calcium supplements in another effervescent composition –let alone an effervescent composition that includes glucosamine and chondroitin. In addition, Fox discloses that his compositions are substantially free of sodium and potassium carbonate and bicarbonate. As such, nothing in Fox provides the skilled artisan with any reason or motivation to add a secondary calcium source in general, or calcium lactate in particular, to the effervescent composition of Phillips. Therefore, Fox fails to include any reason, suggestion or motivation to modify the effervescent composition of Phillips to include calcium lactate. Accordingly, a *prima facie* case of obviousness of claim 6 has not been made. For at least these additional reasons, Applicants submit that the rejection of claim 6 under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of Fox is unwarranted and respectfully request that it be withdrawn.

Claim 7 is distinguishable over the proposed combination of Phillips in view of Liang et al. and further in view of Fox for at least the same reasons set forth above in distinguishing claim 6. Claim 7 is distinguishable over the proposed combination of Phillips in view of Liang et al. and further in view of Fox for at least the following additional reasons. Claim 7 depends from claim 1 and further specifies that the effervescent composition includes at least 5 % by weight calcium lactate based on the total weight of the effervescent composition and no greater than 10 % by weight calcium carbonate based on the total weight of the effervescent composition. The composition of the Example of Phillips includes 0.94 % calcium carbonate. Fox discloses that calcium carbonate is the primary source of calcium and can provide 100 % of the calcium. Fox further discloses that the secondary source of calcium provides no more than 30 % of the soluble calcium. In other words, the compositions disclosed by Fox include a secondary source of calcium in an amount that is significantly less than that of the primary source. Nothing in Fox teaches or suggests including more calcium lactate than calcium carbonate in an effervescent composition. Accordingly, the skilled artisan would have no

reason to modify the composition of Phillips to include at least 5 % by weight calcium lactate. For at least these additional reasons, Applicants submit that the rejection of claim 7 under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of Fox is unwarranted and respectfully request that it be withdrawn.

Claims 8 and 9 stand rejected under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of U.S. Patent No. 1,616,587 (Little).

Little is directed to an improved method of manufacturing effervescent alkali compounds. Little discloses that small additional parts of sodium chloride, magnesium sulphate or lactate and sodium phosphate can be included in their composition. According to Little, "The quantities of magnesia, phosphoric acid, chlorine, potash and lime may be calculated to approximate the relative proportions of these elements in the blood or serum. Thus the alkalies [*sic*] administered are balanced and on a rational basis related to the basal requirements of the body." Little, col. 1, lines 18-24.

The rejection of claims 8 and 9 under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of Little is based on the above-premise that the proposed combination of Phillips and Liang et al. teaches or suggests the effervescent composition of claim 1. Since this premise has been refuted, the rejection of claims 8 and 9 cannot stand. Applicants submit, therefore, that the rejection of claims 8 and 9 under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of Little is unwarranted and respectfully request that it be withdrawn.

Claim 8 is further distinguishable over the proposed combination of Phillips in view of Liang et al. and further in view of Little for at least the following additional reasons. Claim 8 is directed to the effervescent composition of claim 1 and further recites that the composition includes magnesium. Little is focused on a new method of manufacturing effervescent alkali compounds, which is asserted to enable manufacturers to dispense with the use of vacuum driers. The alkali compounds are described as effervescent salts. Little describes a specific composition for use in achieving his method of manufacturing effervescent salts. The March 26th Office action, through reference to the October 6th Office action, takes the position that it would have been obvious to incorporate magnesium sulfate into the effervescent composition of Phillips motivated by the desire to balance physiological magnesium levels in the user. See, October 6th Office

action, page 8. Little is making an effervescent salt, which might be one reason that he is concerned with administered alkalis being balanced. Little does not teach or suggest that such a concern exists with compositions that include glucosamine and chondroitin. Likewise, Phillips does not teach or suggest that he has a desire to balance magnesium levels. The fact that Little may have such a desire is of no moment. Nothing in Little teaches or suggests that there is a need to balance physiological magnesium levels in compositions that include chondroitin and glucosamine. Accordingly, Little provides no reason to the skilled artisan to *sua sponte* add magnesium to the composition of Phillips. For at least these additional reasons, Applicants submit that the rejection of claims 8 and 9 under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of Little is unwarranted and respectfully request that it be withdrawn.

Claims 16-18 stand rejected under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of Fox and Little.

The above discussions of Phillips, Liang et al., Fox and Little are incorporated herein.

Claim 16 is directed to an effervescent composition that includes glucosamine, chondroitin derived from a bovine source, calcium lactate, magnesium sulfate and an effervescent agent. As established above, the proposed combination of Phillips, Liang et al. and Fox does not teach or suggest an effervescent composition that includes glucosamine, chondroitin derived from a bovine source and calcium lactate.

Little does not cure the deficiencies of Phillips, Liang et al. and Fox. Little is focused on a new method of manufacturing effervescent alkali compounds, which is asserted to enable manufacturers to dispense with the use of vacuum driers. The alkali compounds are described as effervescent salts. Little describes a specific composition for use in achieving his method of manufacturing effervescent salts. The March 26th Office action, through reference to the October 6th Office action, takes the position that it would have been obvious to incorporate magnesium sulfate into the effervescent composition of Phillips motivated by the desire to balance physiological magnesium levels in the user. See, October 6th Office action, page 8. Little is making an effervescent salt, which might be one reason that he is concerned with administered alkalis being balanced. Little does not teach or suggest that such a concern exists with compositions that include

glucosamine and chondroitin. Likewise, Phillips does not teach or suggest that he has a desire to balance magnesium levels. The fact that Little may have such a desire is of no moment. Nothing in Little teaches or suggests that there is a need to balance physiological magnesium levels in compositions that include chondroitin and glucosamine. Accordingly, Little provides no reason to the skilled artisan to *sua sponte* add magnesium to the composition of Phillips. Therefore, the proposed combination of Phillips, Liang et al., Fox and Little fails to teach or suggest the effervescent composition of claim 16. Applicants submit, therefore, that the rejection of claim 16 under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of Fox and Little is unwarranted and Applicants respectfully request that it be withdrawn.

Claims 17-18 are distinguishable under 35 U.S.C. § 103 over Phillips in view of Liang et al. and in further view of Fox and Little for at least the same reasons as set forth above in distinguishing claim 16.

Applicants do not comment further on specific features of the dependent claims and do not acquiesce to the assertions contained in the March 26th Office action, since these issues are presently moot in light of the above analysis.

The claims now pending in the application are in condition for allowance and such action is respectfully requested. The Examiner is invited to telephone the undersigned should a teleconference interview facilitate prosecution of the application.

The Commissioner is hereby authorized to charge any additional fees that may be required and to credit any overpayment to Deposit Account No. 501,171.

Respectfully submitted,

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